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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,038	08/09/2001	Hisatomi Ito	NANP110US	4720
23623	7590	06/03/2005	EXAMINER	
AMIN & TUROCY, LLP 1900 EAST 9TH STREET, NATIONAL CITY CENTER 24TH FLOOR, CLEVELAND, OH 44114			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/927,038

Applicant(s)

ITO ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4,5,9-12,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,9-12,14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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***Detailed Action***

The following is responsive to applicant's amendment received Feb. 23, 2004.

Claims 1-3, 6-8, 13 are cancelled. No new claims are added. Claims 4, 5, 9-12, 14, 15 are currently pending.

All previous rejections of claims 9-10 set forth in paragraphs 1-3 of the office action mailed Dec. 17, 2003 are withdrawn in view of applicant's amendment and the remarks contained therein.

However, the indication of allowability of claims 4, 5, 11, 12, 14, 15 is withdrawn in view of newly discovered prior art.

***New Ground(s) of Rejection***

***Claims Rejection(s)—35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 4, 5, 9-12, 14, 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Guthrie et al., 6,251,400 B1.

Guthrie et al. disclose a method of treating individuals suffering from neoplastic diseases, hypercholesterolemia or cardiovascular diseases or a method of treating individuals at a high risk for developing neoplasias or hypercholesterolemia by

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administering to the individual a compositions comprising polyphenolic flavonoid citrus compounds such as tangeretin or nobiletin which are extracted from tangerines. Please see the abstract; col. 1, lines 60-65; col. 5, lines 9-56; col. 7, lines 20-23; col. 13, lines 4-10.

The claims are anticipated by Guthrie et al. because Guthrie et al. teach administration of an identical composition containing an extract from tangerines (nobiletin or tangeretin) to a subject using applicant's claimed method steps. Therefore, extension of neurites and treatment of encephalic ischemia would be inherent.

Concerning claims 11 and 14, contact with neurocytes is inherent in the methods of Guthrie et al., since contact would also be achieved subsequent to the administration of the citrus compounds to the a subject.

Finally, concerning Guthrie's disclosure of additional compounds such as tocotrienols, please note that the claims recite "comprising" language. According to the MPEP 2111.03, "[t]he transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research

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Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). In this case, the claims do not exclude the additional compounds, i.e. tocotrienols, disclosed by Guthrie et al.

### ***Conclusion***

Claims 4, 5, 9-12, 14, 15 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should


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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM   
May 31, 2005

  
**REBECCA COOK**  
**PRIMARY EXAMINER**  
**GROUP 1200/1614**